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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,108	01/25/2002	Geert Platinck	D00590.70011.US	1549

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,108

Applicant(s)

PLAETINCK ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-29 is/are allowed.
- 6) ☒ Claim(s) 1-12 and 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2005 has been entered.

DETAILED ACTION

This application filed January 25, 2002, is a divisional of 09/347,311, filed July 2, 1999.

Applicants amendment filed June 20, 2005 has been received and entered. Claims 42-53 have been canceled. Claims 1-41 are pending.

Election/Restrictions

As indicated previously Groups I-III were rejoined.

Claim 1-41 are currently under examination as they are drawn to a micro-organism comprising an expression vector that when expressed produces double stranded RNA and to use of said product in a method for reducing the expression of a gene of interest in *C. elegans*.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The request to consider the IDS filed because the references are available in related applications is noted. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

As noted in the advisory action, regarding the claim for priority, while it was not previously indicated by Applicants in the instant application, related application 09/347,311 has been reviewed for the presence of the certified copies of the priority documents of the foregoing priority documents. A copy of both documents are present. Further, in light of the evidence in the declaration and preliminary amendments claiming priority of the parent application in which these documents are found, Applicants arguments that the claim for priority is correct and does not require a petition is found convincing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-41 rejected under 35 U.S.C. 102(a) as being anticipated by Timmons *et al.*

(Nature 395:854, (October 1998)) is withdrawn.

In light of the new priority date accorded the instant application, the rejection made under 35 USC 102(a) over Timmons *et al.* has been obviated. The new priority date July 3, 1998, antedates the publishing date of Timmons *et al.* October 1998.

Claims 1-29 rejected under 35 U.S.C. 102(e) as being anticipated by Fire *et al.* (US Patent 6,506,559 B1) is withdrawn.

Applicants note the pending claims each require that the dsRNA be introduced into *C. elegans* by feeding the *C. elegans* a micro-organism expressing said dsRNA (see independent claims 1, 2, 13 and 14), and argue that that Fire *et al.* does not enjoy benefit of priority to provisional application 60/068,562 because this embodiment is not taught in the provisional application. Upon review of the '562 disclosure, Examiner agrees that the methodology of providing the dsRNA in the form of a micro-organism expressing said dsRNA in the food source of *C. elegans* is not recited nor specifically contemplated in the '562 disclosure. Fire *et al.* provide support for providing the dsRNA externally (see page 12, lines 1-6 of '562), however there is no contemplation that this done using a micro-organism expressing said dsRNA, and

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methods related to delivery focus primarily on methodology for providing a form of purified dsRNA (see page 12, lines 7-12 of '562).

Claims 30-41 stand rejected under 35 U.S.C. 102(e) as being anticipated by Fire *et al.* (US Patent 6,506,559 B1).

With respect to independent claim 30, which is drawn to a product encompassing a micro-organism that comprises an expression vector that generates the dsRNA, review of the Fire *et al.* disclosure of '562 finds support for priority. As acknowledged above, Fire *et al.* does not contemplate or appreciate that bacteria expressing the dsRNA can be used simultaneously as a food source and a source of to the dsRNA. However, Fire *et al.* does contemplate the use of bacteriophage RNA polymerases for generating dsRNA, in particular the use of T7, T3 and SP6 promoters for the expression of dsRNA (page 11), highlighting the construction and use of expression vectors known in the art at the time of filing (page 11). More specifically, Fire *et al.* teach that the dsRNA can be synthesized either *in vivo* or *in vitro*, and when practiced *in vivo* the appropriate expression vector comprising the appropriate regulatory region should be provided to transcribe and generate the RNA strand(s) (page 7, lines 16-19). Accordingly, it is found that Fire *et al.* (US Patent 6,506,559 B1) enjoys the claim of benefit of priority of December 23, 1997, given the guidance in the provisional disclosure '562 for the use of bacteria to generate dsRNA.

Claims 1-4, 6-10, 30, 32-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenner as evidenced by Derrick *et al.*

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Claim 1 encompasses feeding *C. elegans* an organism that expresses dsRNA (active step of the method) in order to introduce said dsRNA into *C. elegans* (preamble). The claim does not require any functional affect of the dsRNA on *C. elegans* nor set forth any specific structural limitation on the dsRNA being expressed. In this case the broadest reasonable interpretation encompasses allowing *C. elegans* to be cultured on a micro-organism such as *E. coli*. *E. coli* use promoters to express RNA the ultimately form dsRNA structures such as the lac operon or tRNAs as exemplified by Derrick *et al.* Various endogenous *E. coli* genes when expressed form dsRNA structures, and transcription of these genes is dependent on the presence of a promoter and the relevant transcriptional factors. Brenner teaches a method of culturing *C. elegans* wherein the *C. elegans* culture is maintained on a lawn of *E. coli* bacteria (page 73, Materials and Methods section). Since there is no functional nor structural requirement beyond feeding *C. elegans* a micro-organism that produces dsRNA, Brenner anticipates the claimed methods. Further, since the only requirement of the product is that it produces dsRNA, the product claims are also anticipated by the OP50 strain of *E. coli* taught by Brenner.

Claims 1-4, 6-10, 30, 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kessin *et al.*

As reasoned above, the broadest reasonable interpretation encompasses allowing *C. elegans* to be cultured on a micro-organism with the limitation that the micro-organism produces dsRNA and that it is taken up by the *C. elegans*. Kessin *et al.* teach a method of culturing *C. elegans* with the slime mold *Dictyostelium*. Kessin *et al.* provide evidence that cultures with the slime mold results in its uptake by *C. elegans* (see figure 1 for example). Since

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there is no functional nor structural requirement beyond feeding *C. elegans* a micro-organism that produces dsRNA, Kessin *et al.* anticipates the claimed methods, and the product claims are also anticipated by the *Dicyostelium amoebae* taught by Kessin *et al.*

Conclusion

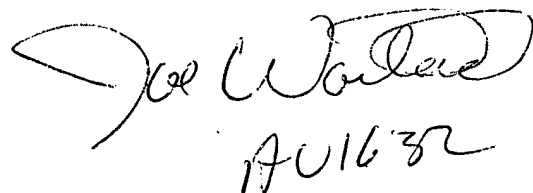
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



Joe Woitach
AU 16 '32